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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 99D-5347

"Precautionary Measures to Reduce the Possible Risk of Transmission of Zoonoses by Blood and Blood Products from Xenotransplantation Product Recipients and Their Close Contacts"

To Whom It May Concern:

The proposed guideline to "indefinitely defer" blood donations from xenotransplantation recipients, their close contacts, and relevant hospital and laboratory personnel is inadequate and has no chance of protecting the U.S. blood supply as currently written.

Only a national computerized name-based registry would allow the identification of these people, to prevent them from donating blood. However, such a registry would be unduly invasive of privacy and restrictive of liberty; its procedures cannot be legally enforced; it would be expensive to set up and manage and would always be vulnerable to human error.

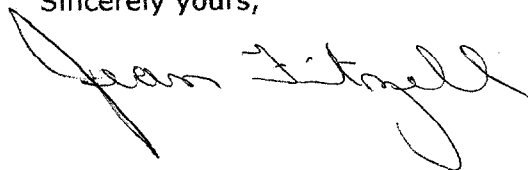
Moreover, the proposed guideline ignores the fact that some viruses are latent. Symptoms of disease from a pig virus, for example, may not manifest themselves for decades after infection, with devastating consequences for the blood supply. The guideline also arbitrarily ignores the fact that some viruses may be transmitted like the common cold. Xenograft patients, therefore, could transmit zoonotic diseases even to casual contacts who may unknowingly donate blood while infected with a new pig virus.

Since humans have been receiving cells, tissues and organs from animals for decades, all xenograft guidelines are being proposed in hindsight. The absence of national and international name-based registries for xenograft patients and their contacts is astonishing, since these people may have already engaged in risky behaviors and/or donated blood.

The threat of "mad cow disease" has already reduced the number of blood donors in the U.S., Canada and abroad. With the threat of known and unknown xenotransplant-related diseases, and the need to exclude xenograft patients, their contacts, and health care personnel from donating blood, xenotransplantation will have the effect of shrinking the blood donor pool, and will thus exacerbate existing blood shortage problems.

When dealing with infectious diseases, a public policy based on containment is unacceptable. If it truly wanted to protect the blood supply and the public health, the FDA would ban xenotransplantation immediately.

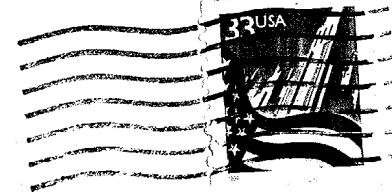
Sincerely yours,



99D-5347

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